



Food and Drug Administration
Rockville MD 20857

Re: ALDARATM
Docket No. 97E-0269
Docket No. 97E-0270

APR 23 1999

The Honorable Q. Todd Dickinson
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the patent term extension applications for U.S. Patent Numbers. 5,238,944 and 4,689,338 filed by Riker Laboratories under 35 U.S.C. § 156. The patents claim the human drug product ALDARATM (imiquimod), new drug application NDA 20-723.

In the October 20, 1998 and October 15, 1998, issues of the Federal Register (63 Fed. Reg. 56035 and 55398), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notices provided that on or before April 19, 1999, and April 13, 1999, 180 days after the publications of the determinations, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day periods for filing a due diligence petition pursuant to these notices have expired and FDA has received no such petitions. Therefore, FDA considers the regulatory review period determinations to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Ted K. Ringsred
3M/Office of Intellectual Property Counsel
P.O. Box 33427
St. Paul, MN 55133-3427

97E-0269

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

100-111111-111111
Memorandum

Date: APR 23 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for ALDARATM

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned drug under the Docket Numbers **97E-0269 and 97E-0270** stating that this particular patent is eligible for regulatory review. The Patent Numbers are **5,238,944 and 4,689,338**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.